NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BRIGHAM AND WOMEN'S HOSPITAL, INC., INVESTORS BIO-TECH, L.P.,
Plaintiffs-Cross-Appellants

v.

PERRIGO COMPANY, L. PERRIGO COMPANY,
Defendants-Appellants

2017-1950, 2017-2021, 2017-2555, 2018-1243

Appeals from the United States District Court for the District of Massachusetts in No. 1:13-cv-11640-RWZ, Judge Rya W. Zobel.

Decided: February 28, 2019

JAMES M. BOLLINGER, Troutman Sanders LLP, New York, NY, argued for plaintiffs-cross-appellants. Also represented by TIMOTHY P. HEATON, PHOENIX S. PAK, GERALD EAMES PORTER; LINDSAY MITCHELL HENNER, DOUGLAS SALYERS, Atlanta, GA.

JEFFREY R. GARGANO, Morgan, Lewis & Bockius LLP, Chicago, IL, argued for defendants-appellants. Also

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Before LOURIE, O'MALLEY, and STOLL, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Perrigo Company and L. Perrigo Company (collectively, "Perrigo") appeal from the order of the U.S. District Court for the District of Massachusetts denying judgment of invalidity as a matter of law of U.S. Patent 5,229,137 (the "'137 patent") on the basis of anticipation and obviousness. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, 280 F. Supp. 3d 192, 205–06 (D. Mass. 2017) ("*Decision*"). Brigham and Women's Hospital, Inc. and Investors Bio-Tech, L.P. (collectively, "Brigham") cross-appeal from the same order granting judgment of noninfringement as a matter of law. *Id.* at 205. Because the district court did not err in its judgment of noninfringement, we *affirm* and do not reach the remaining issues.

I. BACKGROUND

Brigham's '137 patent is directed to a method for treating episodic heartburn by coadministering two known types of heartburn medications, H_2-receptor antagonists (known as H_2-blockers) and antacids. Antacids were known to provide fast but momentary relief from heartburn; in contrast, H_2-blockers were known to provide slower but longer-lasting relief. Critically, the method of treatment as claimed requires that coadministering an antacid and H_2-blocker achieves a certain clinical result: "*immediate and sustained relief* from pain, discomfort and/or symptoms associated with episodic heartburn." '137 patent col. 7 ll. 23–25 (emphasis added). The dispositive issue on appeal is whether Perrigo's product meets the "immediate and sustained relief" limitation.

A.

Claim 1 of the '137 patent is the sole independent claim asserted by Brigham and reads as follows:

> 1. A method of providing *immediate and sustained relief* from pain, discomfort and/or symptoms associated with episodic heartburn in a human, said method comprising:
>
> orally administering to a human together or substantially together an antacid in an amount effective to substantially neutralize gastric acid and a histamine H_2-receptor antagonist in an amount effective to substantially inhibit or block gastric acid secretion for providing the human with immediate and sustained relief from pain, discomfort and/or symptoms associated with episodic heartburn, the immediate and sustained relief provided lasting longer in duration than when the human is orally treated with only the antacid and the immediate and sustained relief provided being faster than and lasting at least about as long in duration as when the human is orally treated with only the histamine H_2-receptor antagonist.

Id. col. 7 ll. 23–42 (emphasis added). The specification defines "immediate and sustained relief," disclosing:

> It should therefore be appreciated that by the term "immediate and sustained relief," *it means herein immediate, temporary and sustained relief which starts within about 5-10 minutes following ingestion of the active ingredients and continues and remains constant for at least about 4-6 hours after ingestion of the active ingredients*; the actual ingredients being an antacid and a histamine H_2-receptor antagonist.

Id. col. 3 ll. 22–29 (emphasis added).

B.

The '137 patent was filed on May 6, 1992, issued in 1993, and expired on May 6, 2012. Brigham exclusively licensed the patent in 1996 to Johnson & Johnson Merck Consumer Pharmaceuticals ("J&J"), also giving J&J the right to pursue any infringement claims. In December 2004, Perrigo sent Brigham a Paragraph IV notice letter informing Brigham that it had submitted an Abbreviated New Drug Application ("ANDA") to market a combination H_2-blocker/antacid tablet prior to the expiration of the '137 patent, and Brigham relayed this information to J&J soon thereafter. J&J declined to assert the '137 patent against Perrigo but did sue on a different patent. Perrigo prevailed and then launched its generic product in 2008. Several years later, in 2013, Brigham brought the present suit accusing Perrigo's generic product of infringing the '137 patent's independent claim 1 and dependent claims 4, 5, 6, 7, and 12. Perrigo counterclaimed, asserting that the '137 patent was invalid as anticipated and obvious.

At claim construction, the district court construed the term "immediate and sustained relief" to mean "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5–10 minutes following ingestion of the active ingredients and continues for at least about 4–6 hours." J.A. 1380–82; *Decision*, 280 F. Supp. 3d at 200.

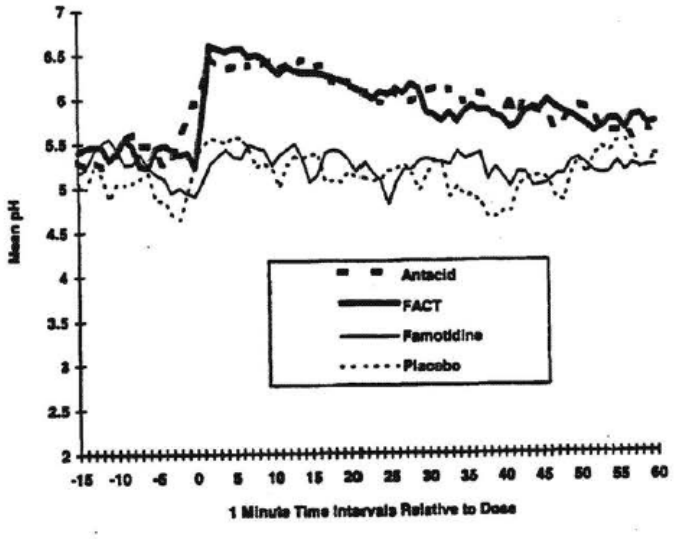
The parties proceeded to trial. A key dispute was whether Perrigo's generic product provided immediate relief as defined by the '137 patent. The main evidence regarding this limitation came from clinical data underpinning J&J's branded H_2-blocker/antacid product, Pepcid Complete®. Brigham argued that the clinical data demonstrated that Pepcid Complete® provides immediate relief, and since Perrigo's generic product has the same active ingredients and dosages as Pepcid Complete®, Perrigo's generic product must also provide immediate relief.

The clinical data came from three studies presented in the New Drug Application ("NDA") for Pepcid Complete®. The first, Study 98, measured 23 qualifying patients' esophageal and stomach pH levels after administering Pepcid Complete® and compared changes in these pH values to controls (an antacid or H_2-blocker alone, or a placebo). Undisputedly, lower (more acidic) esophageal pH may correspond to episodic heartburn, which results from reflux of stomach acid into the esophagus that can cause pain associated with episodic heartburn. In the study, "[a]n episode of acidic reflux was counted as a drop from pH 5 or more to 4 or below . . . ." J.A. 7044. The study was designed to show that Pepcid Complete® would raise esophageal pH faster than an H_2-blocker alone and comparably fast to an antacid alone.

Although the NDA's description of Study 98 does not directly state whether Pepcid Complete® provided symptomatic relief from episodic heartburn starting within about 5–10 minutes, as required by claim 1, the NDA does include a figure of the patients' mean esophageal pH measured over one minute intervals before and after administration of an antacid, Pepcid Complete® ("FACT"), an H_2-blocker ("famotidine"), or a placebo. We reproduce this figure—Figure 7—below:

Figure 7

Esophageal pH Means at 1-Minute Time Intervals Relative to Dose: 0 to 60 Minutes Postdose (n=23) (Protocol 098)



J.A. 7044.

At trial, Brigham's fact and expert witness and the inventor of the '137 patent, Dr. M. Michael Wolfe, testified concerning Figure 7. He opined that "the antacid, whether it was in the combination or by itself, the pH rapidly rose in the esophagus, and it persisted." J.A. 7721. With respect to the claimed immediate relief from episodic heartburn, Dr. Wolfe further attested that "the increase in pH is what we're aiming for. It's mopping up of the acid that's present there. If you mop it up, it's going to relieve symptom; it's going to start to relieve symptoms fairly quickly." *Id.*

In addition to the data from Figure 7, Study 98 also reported the number and duration of esophageal reflux episodes that occurred in the hour after administration of the drugs. On average, patients experienced between 2 and 5 esophageal reflux episodes over the measurement period.

In addition to the pH study, the NDA included two symptom relief studies, Studies 110 and 127. Study 110

measured "adequate relief for *onset* of effect within 2 hours, and for *duration* of effect the number of episodes of heartburn adequately relieved for at least 7 hours." J.A. 7067. Adequate relief from heartburn, as determined by a patient's own assessment, was first measured fifteen minutes after administration of one of the drugs listed above. Results are shown in the table reproduced below:

NUMBER AND (CUMULATIVE %) EPISODES ADEQUATELY RELIEVED IN 1231 PARTICIPANTS TREATED

	FACT	FCT	antacid	Placebo
adequate relief	n = 305	n = 311	n = 308	n = 307
at (minutes)	*1205 episodes*	*1229 episodes*	*1212 episodes*	*1217 episodes*
15	322 (27.0%)	249 (20.3%)	301 (25.1%)	191 (15.7%)
30	222 (45.3%)	215 (37.8%)	190 (40.9%)	210 (33.0%)
45	234 (64.6%)	257 (58.6%)	200 (57.4%)	203 (54.4%)
60	172 (78.8%)	190 (73.9%)	159 (70.5%)	203 (71.2%)
120	77 (85.3%)	94 (81.5%)	102 (78.8%)	(77 (77.5%)

J.A. 7068.

Study 127 was similar to Study 110. It also measured "adequate relief" beginning fifteen minutes after administration. Table 8, reproduced below, displays the results:

Table 8
Study MRL Protocol 127
Onset Data
NUMBER AND CUMULATIVE % EPISODES ADEQUATELY RELIEVED
ALL-PATIENTS TREATED APPROACH (N=1618)

Adequate Relief At:	FACT n=406 Tot Eps†=1585		FAMOTIDINE 10-mg FCT n=406 Tot Eps=1598		ANTACID 21 mEQ n=407 Tot Eps=1565		PLACEBO n=399 Tot Eps=1533	
	n	cum %‡	n	cum %	n	cum %	n	cum %
15 mins	540	33.7	430	27.3	508	32.4	386	25.4
30 mins	291	52.4	304	46.6	259	48.8	265	42.7
45 mins	284	70.5	279	63.8	281	66.9	291	61.7
60 mins	188	82.2	170	74.3	188	78.7	187	73.7
120 mins	72	86.8	91	79.9	81	84.0	74	78.5
>120 mins	210	100.0	324	100.0	248	100.0	330	100.0

† Eps = episodes
‡ Cumulative percentages are "patient-based."
Based on sponsor's table 13

J.A. 6999.

At trial, Dr. Wolfe testified that the parameter measured in Studies 110 and 127—adequate relief at 15 minutes—would "correlate to immediate relief" within 5–10 minutes, but he admitted that the two parameters were different. J.A. 7847–48.

The jury returned a verdict finding that the asserted claims of the '137 patent were not invalid, that Perrigo's generic product infringed each asserted claim, and that Perrigo's infringement was willful. The jury awarded Brigham damages of about $10 million. The district court entered judgment consistent with the verdict on December 19, 2016, but without specifying damages or resolving Brigham's claim for enhanced damages. J.A. 8739.

C.

Several days after the judgment, on December 23, 2016, both parties jointly requested the district court to extend various deadlines for filing post-trial motions. The joint request suggested a deadline for Perrigo's motions for judgment as a matter of law ("JMOL") of January 24, 2017. The court granted the extensions in full.

Perrigo then moved for JMOL of noninfringement and invalidity on the date of the revised deadline. Brigham also then moved for enhanced damages. Additionally, in Brigham's opposition to Perrigo's JMOL motions, Brigham contended that Perrigo's motions were untimely under Rule 50(b). Soon afterwards, in February 2017, Perrigo noticed an appeal from the district court's December 19 judgment.

Several months later, the district court resolved the parties' pending motions. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, 251 F. Supp. 3d 285 (D. Mass. 2017) ("*April Decision*"). The court ruled that its December 19, 2016, judgment was final except for an accounting and therefore triggered the 28-day mandatory deadline set forth in Rule 50(b) for renewed motions for JMOL. *Id.* at 289–90. The 28-day deadline fell on January 17, 2017, a week earlier than the agreed-upon day on which Perrigo renewed its JMOL motions. While the court recognized that it had blessed the January 24 deadline, the court concluded that it had lacked authority under the Federal Rules to do so. *Id.* at 290–91 (citing Fed. R. Civ. P. 6(b)(2)). The court thus

denied Perrigo's motions for JMOL and its notice of appeal as untimely. *Id.* at 292. Finally, the district court denied Brigham's motion for enhanced damages because it found that Perrigo's conduct was not egregious. *Id.* at 293–94.

Perrigo again moved for JMOL and noticed a second appeal on May 19 and May 11, 2017, respectively, this time from the district court's April decision. Brigham then moved to dismiss for lack of jurisdiction, arguing that Perrigo failed to timely file its JMOL motions and notice of appeal. In a single-judge order, we denied the motion. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, No. 2017-1950, -2021, slip op. at 4 (Fed. Cir. June 21, 2017), ECF No. 33 ("*Jurisdiction Decision I*"). We concluded that the district court's December 19 judgment was not final because it did not resolve Brigham's claim for enhanced damages. *Id.* at 3. Although we observed that Perrigo could have appealed from the December 19 judgment under 28 U.S.C. § 1292(c), we held that Perrigo was not obliged to do so because such an appeal from a non-final judgment "is permissive, not mandatory." *Id.* (quoting *DNIC Brokerage Co. v. Morrison & Dempsey Comm'cns Inc.*, No. 90-1389, 1991 WL 335745, at *1 (Fed. Cir. Apr. 25, 1991)). We held that "[w]hat matters is that [Perrigo] filed a timely appeal once all the issues were resolved by the April 24, 2017 decision." *Id.* We thus consolidated both of Perrigo's appeals and deactivated them pending the district court's consideration of certain unresolved motions. *Id.* at 4.

Brigham moved for panel reconsideration. A three-judge panel reaffirmed our original decision. *Brigham & Women's Hosp., Inc. v. Perrigo Co.*, No. 2017-1950, -2021, slip op. at 8–9 (Fed. Cir. Aug. 2, 2017), ECF No. 38 ("*Jurisdiction Decision II*").

D.

The district court then considered the pending motions and granted JMOL of noninfringement because it concluded that Brigham failed to present sufficient evidence of

direct infringement. *Decision*, 280 F. Supp. 3d at 199. Specifically, the court determined that the clinical evidence did not demonstrate that Pepcid Complete® provided immediate relief from episodic heartburn. *Id.* at 202.

The district court first assessed Study 98 and Dr. Wolfe's related testimony concerning Figure 7, including his contention that Figure 7 showed immediate relief through its rapid rise in esophageal pH after administering Pepcid Complete®. However, the court observed that Study 98 defined an episode of acid reflux as requiring esophageal pH to go to 4 or below, but the average pH values in Figure 7 never did so. *Id.* at 202. And, as the study did not otherwise purport to correlate pH recordings to heartburn severity or other symptoms, the court concluded that Figure 7 did not prove that patients in the study were provided with immediate relief. *Id.*

The district court next considered the symptom relief studies. Because these studies indisputably measured a parameter different from the claimed immediate relief—"adequate relief" at 15 minutes, not the start of relief within 5–10 minutes—the court determined that the symptom relief studies also did not support the infringement verdict. *Id.*

Given Brigham's proffered evidence of infringement, the district court concluded that "no reasonable jury could have found direct infringement and Perrigo is entitled to judgment as a matter of law" of noninfringement with respect to claim 1. *Id.* It similarly followed that Brigham could not prove direct infringement of the dependent claims. *Id.* Consequently, the court vacated the jury's award of damages. *Id.* at 205. The court denied Perrigo's motions for JMOL of invalidity. *Id.* at 204–05.

Perrigo appealed from the district court's denial of JMOL of invalidity and its denial of Perrigo's evidentiary motion. Brigham cross-appealed from the court's grant of JMOL of noninfringement, its denial of enhanced damages,

attorney fees, and pre-judgment interest, and its conclusion with respect to a disputed invention date.

II. DISCUSSION

A. Jurisdiction

Notwithstanding that this court has twice decided that we have jurisdiction over Perrigo's appeal, Brigham maintains that "[t]here is a serious question regarding this Court's jurisdiction to hear Perrigo's appeal." Cross-Appellant Br. 1–2. Brigham points to no error, however, in our decision, and simply requests that we "assure [ourselves] that [we have] jurisdiction to hear the appeals as presented." *Id.* at 2. Presumably, Brigham refers to the timeliness issue. But our prior decisions are law of the case, and we do not disturb them.

Under the law of the case doctrine, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988) (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983)). The underlying principle of the doctrine is self-consistency. *See* Charles Alan Wright et al., 18B Federal Practice & Procedure Jurisdiction § 4478 (2d ed. 2002). "Without something like it, an adverse judicial decision would become little more than an invitation to take a mulligan, encouraging lawyers and litigants alike to believe that if at first you don't succeed, just try again." *Entek GRB, LLC v. Stull Ranches, LLC*, 840 F.3d 1239, 1240 (10th Cir. 2016) (Gorsuch, J.). As the doctrine is directed at the integrity of the judicial process, we may address the law of the case *sua sponte*. *See United States v. Wallace*, 573 F.3d 82, 90 n.6 (1st Cir. 2009).

In two decisions, the latter by a three-judge panel, we decided that Perrigo's appeal in this case was timely but deactivated it to allow the district court to resolve Perrigo's pending JMOL motions. *Jurisdiction Decision I*, slip op. at

3; *Jurisdiction Decision II*, slip op. at 8–9. In accordance with those decisions, the district court resolved those motions, resulting in the judgment now before us. Brigham now invites us to disregard the law of the case and our prior decisions, without articulating any reasons why we should do so.

We decline. We depart from the law of the case only in "extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice.'" *Christianson*, 486 U.S. at 817 (quoting *Arizona*, 460 U.S. at 618 n.8). No such circumstances are evident here. The prior panel concluded that the district court's December 19 judgment was not a final judgment because it did not resolve the issue of enhanced damages, and that Perrigo's appeal from that judgment was therefore interlocutory. *Jurisdiction Decision II*, slip op. at 4–5. While an aggrieved party may appeal under 28 U.S.C. § 1292(c)(2) from a district court's judgment that does not fully resolve damages, *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1309 (Fed. Cir. 2013) (en banc), the panel held that an appeal from such a judgment was permissive, not mandatory. *Jurisdiction Decision II*, slip op. at 8 (citing *DNIC*, 1991 WL 335745, at *1); *see Jurisdiction Decision I*, slip op. at 3. In *DNIC*, we encountered a situation similar to the one here—an untimely appeal from a judgment not specifying damages, but a timely appeal from a later judgment that did specify damages. 1991 WL 335745, at *1. There, we permitted the appeal as to issues from both the earlier and later judgments. *Id.* at *2. We see no clear error or manifest injustice in the prior panel's consistent holding here.

As Brigham has alleged no extraordinary circumstances warranting departure from the law of the case, we conclude that we have jurisdiction over these appeals under 28 U.S.C. § 1295(a)(1). We therefore proceed to the

merits. We decide only the question regarding infringement.[1]

B. Infringement

We review the district court's grant of JMOL of noninfringement under First Circuit law. "In assessing the sufficiency of the evidence, we consider whether, viewing the evidence in the light most favorable to the verdict, a rational jury could find in favor of the party who prevailed." *Soto-Lebron v. Fed. Express Corp.*, 538 F.3d 45, 56 (1st Cir. 2008). JMOL is warranted when the prevailing party's case contained no legally sufficient evidentiary basis for a reasonable jury to find for that party. *Id.*; Fed. R. Civ. P. 50(a)(1). We review the court's grant of JMOL *de novo*. *Soto-Lebron*, 538 F.3d at 56.

At trial, Brigham alleged only literal infringement. Literal infringement is a question of fact and requires every limitation in the claim to be found in the accused

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[1] Under *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993), a judgment of noninfringement does not moot a counterclaim of invalidity. However, "we retain the discretion to limit the grounds upon which appeals are decided." *Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296, 1302 n.1 (Fed. Cir. 2017) (affirming judgment of noninfringement and not reaching issues of validity). Given the facts here, we decline to reach the issues of validity. Perrigo agrees that affirming noninfringement would make it unnecessary to review the patent's validity. Reply Br. 3. And while we recognize the "strong public interest" in resolving questions of patent validity, *Cardinal Chem.*, 508 U.S. at 100, that interest here is minimal because the '137 patent has expired and cannot be asserted against others, there are no pending suits involving the patent, and there are no related patents in examination at the U.S. Patent and Trademark Office.

product. *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1339, 1341 (Fed. Cir. 2016). "If even one limitation is missing or not met as claimed, there is no literal infringement." *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). The patentee has the burden of proving literal infringement by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998).

Brigham argues that the district court erred in overturning the jury verdict and granting JMOL of noninfringement. According to Brigham, the court misinterpreted Figure 7 and improperly dismissed the other studies. Based on the totality of the evidence presented, Brigham asserts that a reasonable jury could have found infringement.

Perrigo responds that the district court properly granted JMOL of noninfringement because none of the evidence presented to the jury demonstrated immediate and sustained relief as claimed in the '137 patent.

We agree with Perrigo that the district court's JMOL of noninfringement was proper. The parties' dispute centers on whether the evidence at trial was sufficient to show that Pepcid Complete®, and by implication Perrigo's generic product, provides "immediate . . . relief from pain, discomfort and/or symptoms associated with episodic heartburn." '137 patent col. 7 ll. 23–25. The district court's construction of this term is undisputed: immediate relief means "relief obtained from pain, discomfort and/or symptoms associated with episodic heartburn which starts within about 5–10 minutes following ingestion of the active ingredients." J.A. 1380–82; *Decision*, 280 F. Supp. 3d at 200. As we discuss, Brigham's evidence was insufficient to show immediate relief as claimed, and no reasonable jury could have found otherwise.

Brigham's infringement case relied primarily on the clinical studies 98, 110, and 127 reported in the NDA for

Pepcid Complete®. Like the district court, we begin with Figure 7 of Study 98, reproduced earlier. Figure 7 depicts mean esophageal pH before and after Pepcid Complete® or a control drug is administered to a set of patients. The sole heartburn symptom related to esophageal pH measured in the study was acidic reflux, and "[a]n episode of acidic reflux was counted as a drop from pH 5 or more to 4 or below." J.A. 7044. None of the curves at any point in Figure 7 depict a mean pH below 4. Nor does the study disclose individual esophageal pH data.

Because Study 98 defined an episode of acidic reflux as requiring a drop in pH to below 4, but the pH curves in Figure 7 never drop below 4, the district court concluded that Figure 7 could not prove that the patients in Study 98 taking Pepcid Complete® were provided with immediate relief from episodic heartburn within 5–10 minutes. *Decision*, 280 F. Supp. 3d at 202. We agree. While Figure 7 does show a rapid rise in esophageal pH after administering Pepcid Complete®, that rise is untethered to any symptomatic relief. It cannot support the jury verdict that Pepcid Complete® provides immediate relief from episodic heartburn within 5–10 minutes. At most, the study suggests that Pepcid Complete® *might* provide immediate and sustained relief; such speculative data, however, cannot sustain Brigham's burden of proof.

Brigham argues that Study 98's definition of an episode of acidic reflux only applies to a prior table showing the number and duration of esophageal reflux episodes, not to Figure 7. Implicit in Brigham's argument is the notion that the investigators defined an episode of acidic reflux in different ways within the same study. Brigham cites no evidence in support of that reading. Moreover, the general definition of an episode of acidic reflux offered in Study 98 does not refer to any particular data or figure, and the study contains no alternative definition. Thus, no reasonable jury could have interpreted the study according to Brigham's newly presented reading.

Brigham also emphasizes that Figure 7 involved patients who generally experienced heartburn. This may be true but it is irrelevant to whether Figure 7 demonstrated immediate relief from heartburn symptoms within 5–10 minutes. The fact that the patients in Study 98 experienced heartburn at some time does not support a finding that the rise in esophageal pH shown in Figure 7 demonstrated the claimed immediate relief.

We next consider Studies 110 and 127, which did report symptomatic relief from heartburn. However, the district court concluded that these studies could not support the infringement verdict because they each measured "adequate relief" beginning at 15 minutes, not immediate relief starting within 5–10 minutes as claimed. *Decision*, 280 F. Supp. 3d at 202. There is no dispute that adequate relief first measured at 15 minutes after administration is a parameter different from relief starting 5–10 minutes after administration. Dr. Wolfe testified as such. J.A. 7846 ("[I]t's onset versus – this is adequate relief. Different parameters."). As Studies 110 and 127 did not measure the result that Brigham claimed in the '137 patent, we agree with the district court that they do not support the jury verdict.

On appeal, Brigham argues that the evidence of adequate relief at 15 minutes necessarily showed onset of relief within 5–10 minutes. But at most, Dr. Wolfe's testimony only indicated that the measured parameter would "correlate to" the claimed result. J.A. 7847 ("'15 minutes would be in the five or ten, around that time.' So that would correlate to immediate relief."). Data merely correlating to the claimed limitation does not suffice to prove literal infringement. As Dr. Wolfe testified regarding the data on adequate relief at 30 minutes, "[w]e have no idea" how many patients in Studies 110 and 127 were provided relief starting within 5–10 minutes because that result was not measured or even estimated in either study. J.A. 7791. "Although a jury is entitled to draw reasonable

inferences from circumstantial evidence, reasonable inferences themselves must be more than speculation and conjecture." *Phillip M. Adams & Assocs., LLC v. Dell Comput. Corp.*, 519 F. App'x 998, 1004 n.10 (Fed. Cir. 2013) (quoting *Sunward Corp. v. Dun & Bradstreet, Inc.*, 811 F.2d 511, 521 (10th Cir. 1987)); *see Welch v. Ciampa*, 542 F.3d 927, 935 (1st Cir. 2008) ("Although we give the nonmoving party the benefit of all reasonable inferences, a party cannot rest on 'conclusory allegations, improbable inferences, [or] unsupported speculation' to defeat a motion for summary judgment." (alteration in original) (quoting *McCarthy v. Northwest Airlines, Inc.*, 56 F.3d 313, 315 (1st Cir. 1995))). Because only speculation supports Brigham's contention that data showing adequate relief at 15 minutes implies that relief started within 5–10 minutes, it cannot sustain the jury verdict.

Brigham also points to other evidence purportedly showing that Pepcid Complete® provided the claimed immediate relief—that antacids were conventionally known to act quickly, and that the NDA stated that Pepcid Complete® worked as quickly as an antacid. However, none of this evidence indicates that Pepcid Complete® provides immediate relief within 5–10 minutes as claimed. It therefore cannot support the infringement verdict.

Last, we consider the bare assertion by Dr. Wolfe, the inventor of the '137 patent, that he ingested Perrigo's product after litigation began, and that it provided immediate relief as claimed. J.A. 7760 ("Q. And you have no direct evidence that Perrigo's generic product provides immediate relief within five to ten minutes, correct? A. Well, yeah. I took it myself, and it does."); J.A. 7758. Considering the absence of any clinical data demonstrating the claimed immediate relief, we conclude that this uncorroborated, conclusory, and interested testimony is insufficient to carry Brigham's burden of proof and to sustain the jury verdict. *See Medtronic Inc. v. Boston Sci. Corp.*, 558 F. App'x 998, 1000 (Fed. Cir. 2014) ("The district court correctly noted

that conclusory statements are insufficient to support a verdict finding infringement under the doctrine of equivalents . . . ."); *cf. McKeown v. Bayshore Concrete Prods. Corp.*, 34 F. App'x 741, 743 (Fed. Cir. 2002) ("[U]nsupported, conclusory statements on the ultimate issue of infringement are wholly insufficient to raise a genuine evidentiary dispute for trial.").

Having considered the totality of the evidence, we agree with the district court that Brigham failed as a matter of law to prove that Perrigo's product meets the claimed limitation of providing immediate relief from episodic heartburn within 5–10 minutes. Because each asserted claim contains this limitation, the court did not err in concluding that the infringement verdict and damages award could not stand.

CONCLUSION

We have considered Brigham's remaining arguments but find them unpersuasive. For the foregoing reasons, we *affirm* the judgment of the district court.

AFFIRMED